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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
STIMPERT, PHILIP EARL	
ART UNIT	**PAPER NUMBER**
3746	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/810,123	GREENE ET AL.	
	Examiner	Art Unit	
	Philip Stimpert	3746	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,9-12,23-25 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,9-12,23-25 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 June 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/30/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 October 2008 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 2, 9 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawless et al. (US 5,586,868) in view of Epstein et al. (US 5,464,392) and Jeon et al. (US 2002/0168278).

4. Regarding claim 1, Lawless et al. teach a medical pump (10) for use with a pumping chamber (22) comprising a plunger (30b), or pumping element, adapted to intermittently pressurize the pumping chamber (22) during a pumping cycle and a passive outlet valve (49b), the pumping cycle defining an attempted fluid delivery stroke of the pump. Lawless et al. do teach pressure sensors (74, 75), but do not teach a

position sensor, processing unit, or memory. Epstein et al. also teach a pressure sensor (308), as well as teaching a position sensor (see col. 19, ln. 40-47, col. 20, ln. 21-31) operatively associated with the pumping element (198, operatively associated through pumping piston 272 (also apparently mislabeled 276 in col. 19, ln. 41)) to detect the position of the pumping element (198), a processing unit (48) in electronic communication with the pressure sensor (40 or 308) and the position sensor, and a memory (404) coupled to the processor unit containing programming code executed by the processing unit to establish an expected nominal stroke volume associated with the attempted fluid delivery stroke of the pump, set a first frequency based upon a desired dosage rate (col. 6, ln. 67 "minimum infusion rate," frequency is inherent in a dosage rate with this type of pump), process pressure data from the pressure sensor (40 or 308) and position data from the position sensor (col. 28, ln. 44 to col. 29, ln. 3, also equations 1-2 in col. 31) to determine a calculated actual stroke volume of the pump for a pump cycle and, if the calculated actual stroke volume is greater than a given threshold value, to adjust a stroke frequency (col. 27, ln. 25, adjustment is inherent in the determination of the stroke rate, and effectively any value is a threshold value) of the pump from a first frequency to a second, different frequency (as dictated by the equation in col. 27) to compensate for variation between the calculated actual stroke volume and a desired pump flow rate, so as to more closely approach the target rate during subsequent pumping cycles. One of the primary benefits of the pressure sensing apparatus is the ability to precisely and automatically calculate and control the dispensing of medications to a patient (col. 2, ln. 20-32, also col. 23, ln. 4-11).

However, Epstein et al. require knowledge of the states of the valves of the pump, thus in order to obtain the benefits of the control system of Epstein et al. in the pump of Lawless et al., a method for detecting valve states must be used in order to perform the necessary calculations for control of the pump. Jeon et al. teach valves and pumps for microfluidic systems, and in particular teach a method for determining the state of a passive valve (30, method discussed in paragraph 128) including processing pressure data to indicate when a valve has opened. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the method of determining the state of a passive valve as taught by Jeon et al. in the pump control and monitoring system of Epstein et al. in order to obtain precise, automatic control and monitoring in the pump of Lawless et al. Further, it would be obvious to directly connect the pressure sensor of Epstein et al. to the pumping element (30b) of Lawless et al. in order to obtain the pressure data required by Jeon et al., and to use position sensors to detect the position of the pumping element (30b) of Lawless et al. as taught by Epstein et al.

5. Regarding claim 2, Lawless et al. disclose multiple pressure sensors (74, 75). However, the control system of Epstein et al. requires only a single pressure sensor, thus it would be obvious to use only one sensor, in order to simplify the design and reduce the cost of the parts.

6. Regarding claim 9, Epstein et al. teach that the programming code executed by the processing unit processes pressure data and position data to determine a calculated pressurization volume from a beginning of the compression stroke to the point when the

outlet valve opens, and uses the calculated pressurization volume to determine the calculated stroke volume.

7. Regarding claim 25, Lawless et al. teach a medical pump (10) for use with a cassette (10) having a pumping chamber (22) comprising a pumping element, or plunger (30b), adapted to intermittently pressurize the pumping chamber (22) during a pumping cycle comprising an attempted fluid delivery stroke of the pump, and a passive outlet valve (49b). As modified particularly by Epstein et al., Lawless is modified to include a pressure sensor (308) that would be obvious to position directly connected to and in line with the plunger, as well as teaching a position sensor (see col. 19, ln. 40-47, col. 20, ln. 21-31) operatively associated with the pumping element (198 in Epstein et al., 30b in Lawless et al., operatively associated in Epstein et al. through pumping piston 272 (also apparently mislabeled 276 in col. 19, ln. 41)) to detect the position of the pumping element (198) throughout the pumping cycle, a processing unit (48) in electronic communication with the pressure sensor (40 or 308) and the position sensor, and a memory (404) coupled to the processor unit containing programming code executed by the processing unit to establish an expected nominal stroke volume associated with the attempted fluid delivery stroke of the pump, set a first stroke frequency based upon a desired dosage rate and the expected nominal stroke volume (according to the equation in col. 27), then during a pressurization of the pumping chamber for another attempted fluid delivery stroke, to process pressure data from the pressure sensor (40 or 308) and position data from the position sensor (col. 28, ln. 44 to col. 29, ln. 3, also equations 1-2 in col. 31) to determine a calculated actual stroke

volume (also according to the equation in col. 27, along with those of col. 31) of the pump for the pumping cycle and to adjust a stroke frequency (col. 27, ln. 25, adjustment is inherent in the determination of the stroke rate, and effectively any value is a threshold value) of the pump from a first frequency to a second, different frequency (as dictated by the equation in col. 27)to compensate for variation between the calculated stroke volume and a desired pump flow rate. As further taught by Jeon et al., the programming code executed by the processing unit (48) of Epstein et al. processes pressure data from the pressure sensor (40 or 308) in order to identify when the outlet valve (49b) of Lawless et al. has opened.

8. Claims 10-11, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawless et al. in view of Epstein et al. and Jeon et al. as applied to claim 9 above, and further in view of Madsen et al. (US 4,850,805).

9. Regarding claim 10, the previously applied references do not teach the calculation of stroke volume using a ratio of pumping chamber expansion (hereafter, "pumping chamber expansion" will be used interchangeably with "compliance"). The patent to Madsen et al. is directed to a pump control system for a cassette type medical pump. In particular, Madsen et al. address the problem of accurately measuring the flow volumes of this type of pump, (col. 1, ln. 32-43), especially due to compliance errors. Madsen et al. teach the following method for control of an infusion pump: "The pumping pressure peak during pumping and the pressure minimum during filling are detected to determine the portion of a pumping cycle required to make the transition between these two pressure levels. The difference between the two pressure levels

divided by the transition portion of the pumping cycle gives a measure of the compliance of the pump chamber. The ratio of the compliance measure to the total cycle, when multiplied by the nominal chamber volume, gives a measure of unpumped volume, which is subtracted from the nominal volume to give the volume actually pumped during a pump cycle," (abstract, Madsen et al.). Further, Madsen et al. teach that their "control technique gives particularly precise control at low fluid delivery rates where precision is especially important," (Madsen et al., col. 2, ln. 10-12). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the pressure data collected by the pressure sensor of Epstein et al. in the pump of Lawless et al. to calculate the actual volume of fluid pumped, correcting for compliance, in order to more accurately control volumes pumped at low rates. In particular, it would have been obvious to one of ordinary skill in the art to program the processing unit to determine a change in pressurization volume by subtracting the calculated pressurization volume from a nominal pressurization volume, determine a change in stroke volume by multiplying the change in pressurization volume by a ratio of pumping chamber compliance at the end of the compression stroke of the pump to the compliance at the start of the compression stroke, and determine the calculated stroke volume based on the change in stroke volume.

10. Regarding claim 11, Lawless et al. teach a cassette (10) for defining the pumping chamber (22).

11. Regarding claim 23, Lawless et al. teach a medical pump (10) for use with a cassette (10) having a pumping chamber (22) comprising a pumping element, or

plunger (30b), adapted to intermittently pressurize the pumping chamber (22) during a pumping cycle comprising an attempted fluid delivery stroke of the pump, and a passive outlet valve (49b). As modified particularly by Epstein et al., Lawless is modified to include a pressure sensor (308), as well as teaching a position sensor (see col. 19, ln. 40-47, col. 20, ln. 21-31) operatively associated with the pumping element (198 in Epstein et al., 30b in Lawless et al., operatively associated in Epstein et al. through pumping piston 272 (also apparently mislabeled 276 in col. 19, ln. 41)) to detect the position of the pumping element (198) throughout the pumping cycle, a processing unit (48) in electronic communication with the pressure sensor (40 or 308) and the position sensor, and a memory (404) coupled to the processor unit containing programming code executed by the processing unit to establish an expected nominal stroke volume associated with the attempted fluid delivery stroke of the pump, set a first stroke frequency based upon a desired dosage rate and the expected nominal stroke volume (according to the equation in col. 27), then during a pressurization of the pumping chamber for another attempted fluid delivery stroke, to process pressure data from the pressure sensor (40 or 308) and position data from the position sensor (col. 28, ln. 44 to col. 29, ln. 3, also equations 1-2 in col. 31) to set a stroke frequency (col. 27, ln. 25) for a desired dosage rate based on a nominal stroke volume (A*100 or A*88, col. 31, ln. 12-18), determine a calculated pressurization volume from a beginning of a compression stroke of the pumping cycle to the point when the outlet valve opens (col. 31, relation 1, A*N2), and determine a change in pressurization volume by subtracting the calculated pressurization volume from a nominal pressurization volume (col. 31, relation 1). As

further taught by Jeon et al., the programming code is executed to identify by a slope change in pressure data (paragraph 124) when an outlet valve (49b) of the pumping chamber of Lawless et al. has opened. As further taught by Madsen et al., the programming code is executed to determine a change in stroke volume by multiplying the change in pressurization volume by a ratio of pumping chamber compliance at the end of the compression stroke of the pumping cycle to the pumping chamber compliance at the start of the compression stroke of the pumping cycle, determine a calculated stroke volume based on the change in stroke volume, and adjust the stroke frequency to compensate for variation between the calculated stroke volume and the nominal stroke volume.

12. Regarding claim 24, Lawless et al. teach a cassette (10) for defining the pumping chamber.

13. Claims 12 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawless et al. in view of Epstein et al., Jeon et al., and Madsen et al. as applied to claim 10 above, and further in view of Holst et al. (US 2003/0055375).

14. Regarding claim 12, the previously combined references do not teach the practice of averaging multiple calculated stroke volumes to produce a single calculated stroke volume. The patent to Holst et al. is directed to a pumping control method for a cassette pump. In particular, Holst et al. teach the acquisition of pressure samples, and that “the plurality of samples are averaged to minimize any pressure sensing variations,” (paragraph 35). As discussed above, the calculated stroke volume is in part dependent upon the pressure data. Therefore, it would have been obvious to one of ordinary skill

in the art at the time of the invention to provide a calculated stroke volume comprising multiple calculated stroke volumes averaged together, in order to minimize the effects of pressure sensing variations in the calculations.

15. Regarding claim 31, Madsen et al. teach that the cassette volume (nominal cassette volume) may be empirically determined (col. 8, ln. 24-27). As such, one of ordinary skill would expect measuring error to take place, thus engendering the use of averages (taught above with respect to pressure, but certainly of broader applicability) to minimize the effects of those errors. Therefore it would have been obvious to use an average of multiple nominal pressurization volumes.

Response to Arguments

16. Applicant's arguments filed 30 October 2008 have been fully considered but they are not persuasive.

17. With respect to the argument that Lawless et al. does not teach a plunger, the examiner disagrees. The term “plunger” is a fairly broad term, unmodified. As such, the examiner believes that the actuator (30b) of Lawless et al. substantially constitutes a plunger. Further, while there may be intervening elements between the pressure sensor of Lawless et al. and the actuator, the examiner submits that these elements may still be considered directly connected, given the broadest reasonable interpretation of that limitation.

18. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208

USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

19. In view of the foregoing, the examiner maintains the standing rejections of the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Philip Stimpert whose telephone number is (571)270-1890. The examiner can normally be reached on Mon-Fri 7:30AM-4:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Devon Kramer can be reached on (571) 272-7118. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Devon C Kramer/
Supervisory Patent Examiner, Art Unit 3746

/P. S./
Examiner, Art Unit 3746
16 January 2009